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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/673,795 | 10/20/2000 | Frederic Triebel | 03715.0069 | 4063 |

7590 12/14/2001

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|---|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/673,795 | Applicant(s) TRIEBEL ET AL. | |
|---|---|---|---|
| | Examiner Christopher H Yaen | Art Unit 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30Days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, are drawn to a method of identifying peptide compounds derived from hsp70 having at least one mutation.

Group II, claim(s) 5-6, are drawn to a method of revealing artificial point mutations or modifications, which can increase immunogenicity of peptide compounds derived from hsp70.

Group III, claim(s) 7-11, 13-15, 19-21, 29-31, 32-36, 39-40 are drawn to a peptide compound which comprises a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation; an expression vector used for the expression of a sequence of at least 8 amino acids of hsp70 with at least one mutation; a pharmaceutical composition comprising an expression vector and a carrier a

pharmaceutical composition comprising a peptide compound or a mixture of peptide compounds; pharmaceutical compositions containing adjuvants, vehicles which are compatible with IV subcutaneous, oral, or nasal administration; a pharmaceutical vehicle with different charge characters; and a method of using a peptide with a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation for the manufacture of medicinal products, in combination with radiotherapy and repeated immunization.

Group IV, claim(s) 12, 22, are drawn to a DNA fragment encoding a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation; a pharmaceutical composition comprising a DNA fragment and a carrier.

Group V, claim(s) 16-18, 23, 29-31 are drawn to dendritic cells either loaded with a peptide comprising a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation or transformed with an expression vector that encodes for a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation; a pharmaceutical composition comprising the cells and a carrier; pharmaceutical compositions containing adjuvants, vehicles which are compatible with IV subcutaneous, oral, or nasal administration; and pharmaceutical vehicle with different charge characters.

Group VI, claim(s) 24-28, are drawn to a combination product comprising a peptide with a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation and at least one agent which induces cellular stress.

Group VII, claim(s) 37-38 39-40, drawn to a method of using a peptide with a sequence of at least 8 conserved amino acids of hsp70 having at least one mutation to increase or induce CTL population, in combination with radiotherapy and repeated immunization.

Group VIII claim(s) 41-46, are drawn to a method of producing an antibody that binds hsp70 mutant; a monoclonal antibody which binds to mutated hsp70 fragment, and a diagnostic kit used for detecting cancer.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different groups I and II are directed to methods for identifying peptides that have a mutated sequence of hsp70 sequence or increased immunogenicity. These are unrelated because the outcome of these methods have different effects/results that can be obtained.

Groups III-VI, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different groups are distinct and independent products. Each of these products is independent of the other, wherein none is required for the production

or the use of the other. The products of groups III, VI, V, VI, and VIII, respectively, would be expected to have different structure, function, and divergent classifications. The products are capable of separate manufacture, use, or sale as claimed , and are patentable over each other. The peptide of group III, can be used alone or in conjunction to the DNA fragment or visa versa, the peptide of group III can be loaded or expressed in other cells other the dendritics cells, the combination product can contain another peptide other then the one claimed in group III in combination with other substances that cause cellular stress, and the peptide of group III is not needed to produce the antibody, other sources for antibody creation can be found.

Groups I-II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the mutant peptide can be made be made through a recombinant system, where the mutation is intentionally created followed by screening of the peptide compounds for increased immunogenicity.

Groups I-II and IV-V, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to either method claims or to product claims. The claimed products cannot be used to help determine or assist in the method claims.

Groups I-II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the methods of identifying the hsp70 peptide in groups I and II, although related to groups VI in that the product of group I and II are used in the process of creating groups VI, other methods to obtain the desired product claimed in groups I-II can be used. The peptide can be manufactured synthetically on a peptide synthesizer, with a known sequence modification at particular amino acid residues.

Groups I-II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to two separate methods. Groups I-II are used for the identification of peptides containing mutations of hsp70 while the inventions in group VII are drawn to using the peptide with mutations of hsp70. Although they are related as method of making and method of using, these two methods can be used to make other products and the products can be substituted by other compound/substances.

Groups III-VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products claimed in groups III-VI can all be substituted by other compounds that are capable of stimulating CTL production or population.

Groups VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant the method claimed in group VII has a different function then the method and product claimed in group VIII. The method of producing the antibody to hsp70 and the antibody itself can be used for other purposes other then for the use in therapeutics, such as in laboratory testing.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

GEETHA P. BANSAL
PRIMARY EXAMINER

Christopher Yaen

Art Unit 1642

December 13, 2001